NEVADA DIVISION OF ENVIRONMENTAL PROTECTION
BUREAU OF CORRECTIVE ACTIONS
SPECIAL PROJECTS BRANCH
SUPPLEMENTAL GUIDANCE FOR ASSESSING DATA USABILITY FOR ENVIRONMENTAL INVESTIGATIONS AT THE BMI COMPLEX AND COMMON AREAS IN HENDERSON, NEVADA

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1. Introduction

The Nevada Division of Environmental Protection, Bureau of Corrective Actions, Special Projects Branch (hereinafter "NDEP") has prepared this supplemental guidance to support data usability (DU) evaluations of environmental datasets that will be used to support health risk assessments (HRAs) at the BMI Complex and Common Areas in Henderson, Nevada. The Companies that operate the facilities should be familiar with and utilize the primary guidance documents (USEPA, 1992a, 1992b) as well as supporting guidance documents (USEPA, 1988, 1989, 2000, 2006). As specified in the United States Environmental Protection Agency (USEPA) DU guidance (USEPA, 1992a, 1992b), as well as RAGS Part A (USEPA, 1989), risk assessors should be an integral part of the site characterization process, including the DU evaluation. By preparing this supplemental guidance, the NDEP has presented a simplified version of USEPA's DU evaluation process, while streamlining USEPA's DU evaluation process for use at the BMI facilities. The following text presents summaries of the USEPA DU guidance (1992a), provides recommendations for improvements or enhancements that NDEP expects in a DU evaluation by the Companies, and eliminates or identifies aspects of the USEPA Guidance NDEP considers to be redundant, or duplicates aspects of Data Validation. USEPA's DU guidance is aimed primarily at assuring quality of data one data point, or datum, at a time through an evaluation of the laboratory analysis. This NDEP guidance also adds a simple data analysis component so that the reasonableness of the data can be examined in the context of the conceptual site model (CSM) and the risk assessment endpoint.

2. Summary of USEPA Data Usability Guidance Objectives and Approach

USEPA states in its DU Guidance (1992a) that "data usability is the process of assuring or determining that the quality of data generated meets the intended use." The intended use being risk assessment in this case, the purpose of the USEPA Guidance is "to provide direction for planning and assessing analytical data collection activities for the HRA, conducted as part of the remedial investigation (RI) process." The focus is on the "minimum

requirements for environmental analytical data used in baseline risk assessments." The ultimate goal is to understand the types, quality and quantity of data needed to support a baseline risk assessment, and the impact that the data collection decisions have on the level of certainty of the risk characterization.

USEPA identifies five data quality factors that are frequently encountered in risk assessment: data sources, detection limits, qualified data, background samples, and consistency in data collection. USEPA's DU guidance provides procedures, minimum requirements, and other information to resolve or minimize the effect of these issues on the assessment of uncertainty in the risk assessment. The issues affect both the planning for, and the assessment of, analytical data for use in risk assessments.

1. **Data Sources**: Data users must select sampling and analytical procedures and service providers (e.g., analytical laboratories) appropriate to the data needs of the risk assessment. Practical tradeoffs among detection limits, response time, documentation, analytical costs, and level of uncertainty should be considered prior to selecting sampling designs, analytical methods, and service providers.

2. **Detection Limits**: Analytical methods must be selected that achieve the detection limit that meet the needs of the risk assessment. The type of detection limit, such as method detection limit or sample quantitation limit, should meet the requirements of the data quality decisions that affect the certainty of the risk assessment.

3. **Qualified Data**: Qualified data must be used appropriately in risk assessments. Data are almost always useable in the risk assessment process, as long as the uncertainty in the data and its impact on the risk assessment are thoroughly explained.

4. **Background Samples**: Analytical data reported near method detection limits and sample results qualified during data review complicate the use of background sample data to determine site contamination. Planning for the collection of a sufficient number of background samples from representative locations, and meeting comparability criteria, will increase the certainty in decisions about the significance of site contamination.

5. **Consistency in Data Collection**: All parties collecting environmental analytical data for HRAs should ensure that the assessments are conducted consistently.

The USEPA DU guidance is organized following the sequence of defining, planning, assessing and determining. In USEPA's guidance, the DU Criteria enter the process in both the defining and assessing stages, with the goal of ensuring that data of appropriate type, quality and quantity will be collected, and, once the data have been collected verify that they are of the right type, quality and quantity. Six DU Criteria are identified in USEPA's DU guidance for these two stages:

- Data sources
- Documentation
- Available analytical services in terms of analytical methods and detection limits,

- Data quality indicators,
- Data review, and
- Reports to risk assessor.

The intent is that these criteria address the five major data quality factors previously discussed, as well as other factors that can impact data usability in the risk assessment. The six DU criteria are applied in the defining stage to guide the design of sampling plans and select analytical methods for the data collection effort. The criteria are employed again in the assessing stage to evaluate the usability of the analytical data collected, and of data from other studies and sources, such as site inspections. This NDEP supplemental guidance pertains primarily to data usability issues for assessing data.

USEPA has established guidance for assessing data quality issues in Chapter 5 of their *Guidance for Data Usability for Risk Assessment* (USEPA, 1992a, 1992b; Part A for chemicals and Part B for radionuclides). The USEPA DU guidance provides the basis for identifying and evaluating some of the uncertainties associated with data that are used in the HRA process (USEPA, 1989, 1992). DU evaluation after data are collected is the process of assuring or determining that the quality of data generated meets the intended use. USEPA has established their DU guidance framework to provide risk assessors a consistent basis for making decisions about the minimum quality and quantity of environmental analytical data that are sufficient to support HRA decisions (USEPA, 1992a). Specifically, the USEPA DU guidance provides an explicit set of six DU Criteria that are used to document the usability of site characterization data in the HRA process.

Criterion I **Reports to Risk Assessor:** Data should be reported in a format that provides adequate data and data documentation for the risk assessment.

Criterion II **Documentation**: The objective of the documentation review is to ensure that each analytical result can be traced to a sample location and that the procedure(s) used to collect the environmental samples were appropriate.

Criterion III **Data Sources**: The objective of the data source review is to ensure that the analytical techniques used for the investigation are appropriate to identify Chemicals of Potential Concern (COPCs) for each exposure area and environmental medium of interest.

Criterion IV **Analytical Methods and Detection Limits**: For a chemical result to be usable for assessing risks, the analytical method must appropriately identify the chemical form or species, and the sample detection limit must be at or below a concentration that is associated with risk benchmark levels.

Criterion V **Criterion V: Data Review**: This step consists of the assessment of the quality of analytical results, performed by a professional knowledgeable in the necessary analytical procedure(s).

Criterion VI **Data Quality Indicators**: The data quality indicators (DQI) address field and analytical data quality aspects as they relate to uncertainties in selection of COPCs, exposure point concentrations (EPCs), and risk characterization.

3. NDEP's Approach to Data Usability Evaluation

The objectives of this supplemental guidance for DU evaluation are to identify the minimum requirements that must be met and documented for each of the DU criteria once data have been collected, and to require some simple data analysis to be performed to assure reasonableness of the data in the context of the CSM and the HRA endpoint. The DU criteria for the most part address data one data point, or datum, at a time. The intent of the data analysis component of this NDEP guidance is to also look at the data holistically.

The minimum requirements of the NDEP DU evaluation process are summarized in the following sections. The DU criteria and the data analysis methods are applicable to both site and background data. Also provided as a component of this guidance are DU worksheet templates that can be used with the DU criteria evaluations. Any single worksheet template, or combination of more than one of the worksheet templates, may be used by the Companies in order to document how the DU evaluation was conducted, what the findings were, which data are usable for HRA (and why), and which data are not usable (and why). If none of the provided worksheet templates are used for the DU evaluation, then a worksheet must be provided which provides similar information and detailed documentation of the DU evaluation and its conclusions.

NDEP expects the Companies to follow the USEPA DU guidance, but recognizes the need for this supplemental guidance that is specific to the process that has been laid out for environmental investigations and risk assessments performed by the Companies. This NDEP supplemental DU guidance provides some clarification regarding the following:

- The USEPA DU guidance duplicates some aspects of the data validation process that is currently performed by the Companies, and then reviewed by NDEP;
- The USEPA DU criteria are not sufficiently specific about the relationship between DU and the CSM; and
- The USEPA guidance does not specifically address the importance of some level of data analysis to test the reasonableness of the data as a whole.

In this supplemental guidance, NDEP has avoided duplication between data validation and DU, and provides clarification regarding how some of the DU evaluation criteria should be

used to address compatibility with the CSM. To achieve these goals, the basic requirements specified in the USEPA DU criteria are presented, and NDEP's suggested adjustments to those criteria are explained. First, NDEP summarizes its position on the importance of the CSM in DU evaluation.

4. Importance of the Conceptual Site Model in the Data Usability Evaluation

The site investigation and characterization process begins with collecting and analyzing existing data and developing a CSM (USEPA, 1988;1992a). Initially the CSM relies upon data historically collected at the site and is continually updated as new data are collected. Information is included on the history of the site and on the chemical sources, release and transport mechanisms, pathways, and receptors at a site to develop a conceptual understanding of the site for evaluating potential health risks. (USEPA, 1988, 1989). The CSM should convey (USEPA, 1988 and 1989:

1. known and potential sources of contaminants,
2. release mechanisms and primary media,
3. migration pathways and secondary media that are contaminated or may become contaminated, and
4. receptors and exposure points

The CSM is important for the DU evaluation. It provides a basis for evaluating data in the context of what is thought to be known about the site. The DU evaluation should compare data to the CSM to update or modify the CSM as appropriate, and to set the stage for determining if there are data gaps that require further sampling (and associated iterations in the risk assessment). In particular, the CSM is a tool that should be used in the DU evaluation to make sure that the geographic and source term coverage of the sampling program is appropriate and sufficient. Evaluation of the DU criteria combined with the data analysis required by NDEP should fully support comparison with the CSM and identification of data gaps, if any.

5. Summary of Minimum Requirements of the Data Usability Evaluation Criteria

In this section a summary of each of the six USEPA DU criteria is presented along with the adjustments that NDEP requires for environmental investigations and risk assessments performed by the Companies. Changes suggested by NDEP for the DU evaluation include:

- reference of some aspects of a DU evaluation to the appropriate data validation reports
- addition of some aspects of DU that are related to the CSM
- removal of some redundancies in the criteria

5.1. Criterion I: Reports to Risk Assessor

Reports should include all appropriate data and should include adequate documentation for the HRA. Criterion I relates only to whether the specific report components (for each site characterization report relied upon) are included; evaluation of the content of the report components is addressed in subsequent DU criteria. If specific report components are missing, this should be documented, and the impact upon usability of the data should be discussed in this or other sections of the DU evaluation. The minimum requirements for evaluating the content adequacy of each relevant report available to the risk assessor include identification of the following report components.

1. Site description with detailed map(s) indicating site location (including site boundaries drawn to scale), relevant structures, terrain features, air and water flow (where relevant), and information regarding operative industrial processes (*i.e.*, source locations).

2. Site map with sample locations (including sample identification codes and depths)..

3. Description of sampling design and procedures, including rationale.

4. Description of analytical preparation, extraction and determination methods used and detection limits including sample quantitation limits (SQLs) and detection limits for non-detect data.

5. Results given on a per-sample basis, qualified for analytical limitations and error, and accompanied by SQLs. Estimated quantities of compounds/tentatively identified compounds, where relevant.

6. Field conditions and physical parameter data as appropriate for the environmental media of interest.

7. Quality control (QC) data results for audits, blanks, replicates, and spikes from the field and laboratory.

8. Narrative explanation of qualified data on an analyte and sample basis, indicating direction of bias (if included in the report).

9. Definitions and descriptions of flagged data.

10. Hardcopy or electronic copy of results.

11. Laboratory reports that include: (1) the name and address of the laboratory along with the location where the tests were conducted if different from the address of the laboratory; (2) A unique identification of the test report along with individual and total page numbers to ensure a complete report is provided; (3) The name of the client and project name if applicable.: (3) Identification of each preparation and analysis method used, unambiguous identification of the samples(s) including a link

to the client identifications; (4) Dates of sample receipt, sampling, preparation and analysis; (5) Test results including calibrations and QA/QC results along with raw data (instrument output, chromatograms and/or spectra) ; (6) Units of measurement shall be identified and these must indicate if the results were on a dry weight or wet weight basis where this applies; (7) A narrative that describes the effect that any noncompliance with work plan and laboratory QA/QC has on the sample results along with the name(s), function(s); and (8) signature(s) authorizing the report along with a date of issue.

5.2 Criterion II: Documentation

The objective of the documentation review is to ensure that each analytical result can be traced to a sample location (and time if appropriate), and that the procedure(s) used to collect the environmental samples were appropriate. For this criterion two major site investigation planning documents are used: 1) the Sampling and Analysis Plan, and 2) the Field Sampling and Standard Operating Procedures (FS/SOP). The three acceptable types of documentation used to trace samples and analytical methods are chain-of-custody forms, standard operating procedures (SOPs), and field and analytical records that are developed in the project planning documents.

The minimum requirements of Criterion II are that each sample result can be related to a specific geographic location (in 3 dimensions), time of sampling and analysis, and documentation that ties the sample location to the sample result. A comprehensive sample location figure and associated data summary tables should accompany this component of the DU evaluation.

5.3 Criterion III: Data Sources

The objective of the data source review is to ensure that the analytical techniques used for the investigation are appropriate to identify COPCs for each exposure area and environmental medium of interest, and that appropriate analytical methods have been used. The main focus of this criterion is coverage of the media of interest within the exposure areas. This should include adequate sample coverage of the source areas within the exposure areas, and adequate geographical coverage by media within each exposure area. Spatial plots of the data could be used to support comparison with the CSM (see Section 6). Minimum requirements for this criterion are:

1. Demonstrate that analytical sample data results are produced for each medium of interest within an exposure area;

2. Demonstrate that a broad spectrum analysis is available for at least one sample per medium of interest per exposure area (the broad suite spectrum analysis must cover the source area at a minimum); and

3. Demonstrate that field measurement data are available for physical characteristics of the site, medium, or contamination source where deemed critical to the quantitative evaluation of risk (*i.e.*, fate/transport modeling). Examples include particle size, pH,

soil density, soil porosity, soil moisture content, soil organic carbon content, wind direction and speed, topography, and percent vegetative cover.

5.4 Criterion IV: Analytical Methods and Detection Limits

For a chemical result to be usable for assessing risks, the analytical method must appropriately identify the chemical form or species, and for each chemical, the sample quantitation limit (SQL) or minimum detectable concentration (MDC) must be sufficiently below a concentration or activity that is associated with the chemical's risk benchmark levels (*e.g.*, 1/10 of the benchmark level, where technically achievable). When a COPC is reported as not detected, the result can only be used effectively in the risk assessment if the quantitation limits reported are sufficiently lower than the corresponding risk benchmark level. NDEP has developed Nevada Comparison Levels (NCLs), which are generally based on the USEPA Region VI Medium-Specific Screening Levels (MSSLs), as the appropriate risk benchmark levels for purposes of screening applications such as DU evaluation. It is noted that, as of the publication date of this guidance, the NCLs are the USEPA Region VI MSSLs. It is expected that a NDEP screening guidance will be issued and updated periodically.

The minimum requirements for this evaluation step are:

1. Documentation that routine (*e.g.*, USEPA or ASTM) analytical methods were used to analyze COPCs; and

2. Documentation that SQLs and MDCs meet risk assessment needs.

Note that it is the preference of NDEP that all radionuclide results are presented both with and without the minimum detectable activity or concentration to assist statistical analysis of the data, and that data used for ambient subtractions are also made available in the laboratory reports.

5.5Criterion V: Data Review

This step consists of the assessment of the quality of analytical results, performed by a professional knowledgeable in the necessary analytical procedure(s) and data application (HRA). The names and qualifications of the reviewers should be provided. The requirement for HRA is that only data that have been reviewed according to a specified level or plan (e.g., as specified in data quality objectives (DQOs), field sampling plans (FSPs), sampling and analysis plans (SAPs), standard operating procedures (SOPs) and/or quality assurance project plans (QAPPs)) will be used in the HRA. Any analytical errors, potential data gaps, and/or limitations in the data to be used must be addressed; an explanation for data qualifiers must be included. Details in this regard are generally discussed as a component of Criterion VI.

The appropriate level of review, for each data source, is identified, applied, and documented. The minimum requirement for this DU evaluation criterion is that there be a "defined level of data review for all data" (USEPA, 1992a). The level of review should be adequately described. Minimum requirements for the data review of laboratory and method performance include (USEPA, 1992a):

1. Verification of instrument calibration;

2. Examination of duplicates and measurement of laboratory accuracy using spikes;

3. Examination of blanks for contamination;

4. Assessment of adherence to method specifications and QC limits; and

5. Evaluation of method performance in the sample matrix.

Details regarding review of these and related aspects of the analytical data are usually provided in the Data Validation Summary Reports (DVSRs), and can be referenced to those reports as appropriate.

5.6 Criterion VI: Data Quality Indicators

The data quality indicators (DQI) address field and analytical data quality aspects as they relate to uncertainties in selection of COPCs, and characterization of EPCs, and risk descriptors. The DQIs include completeness, comparability, representativeness, precision, and accuracy. The DQIs and minimum requirements for the DU evaluation are described below. Precision and accuracy are usually addressed in the DVSRs and can be referenced to those reports as appropriate. The risk assessor should use the information provided in the laboratory reports and DVSRs to make ultimate determinations regarding the usability of the data.

5.6.1 Completeness

The evaluation of completeness includes assessment of field sampling and analytical data components. Completeness for field sampling is measured by the total number of acceptable data points and total number of samples collected by medium, source area and exposure area. Completeness also applies to background samples, by medium and environment (*e.g.*, geology). Sampling completeness is important, as a decrease in the number of acceptable samples collected from the number of samples specified in the sampling plan could result in a data gap. Completeness is measured, for risk assessment purposes, by the total number of data points available and acceptable for each COPC for each medium of interest, and for each source area or exposure area of interest. For risk assessment purposes, the adequacy of the number of samples is evaluated in terms of: (1) acceptable uncertainty regarding the identification of COPCs in each environmental medium of interest and within each exposure area; and (2) acceptable uncertainty regarding the estimation of EPC of each COPC within each exposure area.

The minimum requirements for the assessment of completeness are:

1. Percentage of sample completeness should be determined during planning to meet specified performance measures; and

2. 100% of all data for analytes in critical (*i.e.*, background and source-related) samples;

5.6.2 Comparability

Comparability is a critical issue when considering the combination of data sets from different sampling and/or analytical events for the same COPCs. Only comparable data sets can readily be combined for the purpose of generating a single risk assessment decision/calculation. Only comparable background and site datasets can be used for background comparisons. The use of standard sampling and analytical methods simplifies the determination of comparability. All non-routine methods should be specifically evaluated for comparability in the DU evaluation. Sensitivity calculations (detection/concentration/activity limits) should be clearly defined, and also must be comparable between datasets if the datasets need to be combined to support risk assessment. In addition, the geophysical environment must be similar for sample data that are used in the same statistical analysis (e.g., background, site data from different locations).

The minimum requirements for the assessment of comparability are:

1. Common sampling techniques were followed, including the issues of field preservation, filtering/non-filtering, low flow sampling, adding solvents in the field, use of specialized methods (e.g. EnCore™ sampling);

2. Analytical methods used in different data sets for the same chemicals had common analytical parameters;

3. The same units of measure were used in reporting;

4. Similar detection limits or minimum detectable concentration/activity were used for each method and chemical;

5. Equivalent sample preservation, extraction and preparation techniques were used, including clean-up where applicable; and

6. Ensure that the site conditions are similar for sample data that are used in the same data analysis.

5.6.3 Representativeness

Representativeness of data used in risk assessment should be documented. The results of the risk assessment will be biased to the degree that the data do, or do not, reflect the chemicals and concentrations present at exposure points for each exposure area of interest. The CSM should be employed to ensure that sampling locations address sources, chemical release and transport, and exposure points (e.g., appropriate soil depth intervals). In cases where sampling was not specifically designed to characterize representative COPCs and EPCs, it is critical to evaluate the impact on the risk assessment results. Any field quality control (QC) issue identified in the DVSR that would limit or qualify the use of data presented in support

of the HRA should be identified and discussed in the DU evaluation. In addition to sampling strategy issues, analytical data quality should be assessed with regard to representativeness. Sample location, sample collection method, holding time, sample preservation, laboratory sub-sampling, extraction and preparation procedures, and results from analyses of blanks affect the representativeness of analytical data. Reference can be made to the DVSRs where appropriate, but for issues that affect representativeness of the data to support risk-based decisions, further discussion, investigation and explanation is needed beyond the DVSR.

The minimum requirements for the assessment of representativeness are:

1. Sample data are representative of source terms, exposure areas, evaluation areas, and operable units, This applies to all relevant media for site and background data;

2. Evaluation of sample preparation procedures, filtering, compositing, and sample preservation in regard to representativeness; and

3. Documented analytical data as specified in the SAP.

5.6.4 Precision

Precision is a measure of the repeatability of a single measurement and is evaluated from the results of duplicate samples and splits. Precision is determined by evaluating: (1) the sampling variability; and (2) the measurement error. Assessment of sampling variability is critical to identifying the appropriate statistical measures and the number of required samples (USEPA, 1992a). Assessment of measurement error is accomplished by using the results of field duplicate samples as well as laboratory duplicate samples. Field duplicates determine total within-batch measurement error (including analytical error if the samples are also analyzed as laboratory duplicates).

The minimum requirements for the assessment of precision are:

1. One set of field duplicates or more as specified in the SAP;

2. Analytical duplicates and splits as specified in the SAP; and

3. Sampling and analytical precision are quantitated for each laboratory data batch using data for laboratory control versus laboratory control duplicate (LC/LCD) and/or (preferably) data for matrix spike versus matrix spike duplicate (MS/MSD).

For cases where laboratory criteria are not met for precision, rationale for final decisions regarding the usability of a particular data point should be provided.

5.6.5 Accuracy

Accuracy is a measure of overestimation or underestimation of reported concentrations and is evaluated from the results of spiked samples. Accuracy is quantitated for each laboratory data

batch using data for laboratory control (LC) samples and/or (preferably) data for matrix spike (MS) samples.

It is important to note that unless every sample is spiked, spike recoveries indicate only a trend rather than a specific quantitative measure. It is also important to note that the results of the LC sample provide information on recovery of a chemical spike from distilled/deionized water, whereas the results of a matrix spike provide information on recovery of a chemical from the matrix (e.g., soil). Finally, for MS data, it should be documented if the laboratory used a site-specific sample for the MS.

Accuracy is controlled primarily by the analytical process and is reported as bias. Bias is estimated for the measurement process by calculating the percent recovery (%R) for the spiked or reference compound.

Field blanks are evaluated to estimate the potential bias caused by contamination from sample collection, preparation, shipping and/or storage.

The minimum requirements for the assessment of accuracy are:

1. Field spikes to assess accuracy of non-detects and positive sample results if specified in the SAP;

2. Analytical spikes as specified in the SAP;

3. Field and laboratory blanks to assess contamination;

4. Use of routine analytical methods that specify expected or required recovery ranges using spikes/tracers or other QC measures; and

5. No COPCs detected in the blanks above acceptable levels (USEPA, 1992a).

For each data point carried into the HRA database that had laboratory QC issues (*e.g.*, outside control limits, missing QC, missed holding time, or elevated RL) ["Category 1"], provide a discussion of why (even though the required criteria were not met) the data were considered usable, if so. And for each data point identified as unusable and eliminated from the HRA dataset ["Category 2"], a discussion should be included as to why the data point was considered not usable and why elimination of the data point does not lead to a data gap. Provide a list of the specific sample identifications (IDs), and the associated analytes within those sample IDs, that fall into Category 1 and into Category 2, and discuss, for each of the Category 1 and Category 2 data points, why the risk assessor made the decision of whether the data point was usable or not.

6. Data Analysis

The USEPA DU criteria primarily address analytical issues associated with each reported data point. Some consideration is given to the data as a whole when considering

comparability and representativeness DQIs, but the focus is again analytical in the USEPA guidance. NDEP requires the Companies to take a step further to provide a view of the data as a whole so that early detection of data gaps and/or problematic data is possible.

For a single dataset, whether site data or background data, NDEP requires preparation of summary statistics tables to include, at a minimum

- The frequency of detection, the range of the non-detects, and the minimum, median, mean and maximum of the detects.

- Simple plots of the data, such as box plots, quantile plots, histograms, and/or dot plots. These plots should used different symbols for detects and non-detects. Substitution of non-detects at this stage is not preferred. (Note that ½ of the detection limit can be used when preparing a risk assessment, but it is not preferred when presenting raw data.)

- Spatial plots of the data, such as geographic information system (GIS) images with boxes showing raw data, GIS images overlaid by intensity plots (which depict concentration through color intensity of the circle or symbol that represents the sample), bubble plots (which depict concentration through the size of the bubble), or scale plots that use color to depict a range of data for a particular sample (*e.g.*, with cut-offs at the maximum background concentrations or risk thresholds of interest (such as 1/10 of the NCL)).

When two or more datasets are involved, NDEP requires preparation of similar summary statistics tables and plots, however the plots should be side-by-side for the two or more datasets so that direct comparison is facilitated. Other types of analyses can also be considered, such as correlation or regression analysis, temporal plots, depth profiles, depending on the nature of the data and the objectives of the HRA.

The intent of this step of the DU evaluation is to use simple exploratory data analysis to compare data to the expectations of the CSM, to determine if the data adequately represent the source terms and exposure areas or evaluation areas. Comparability issues can also be supported through these data analyses. For example, background data might represent more than one geologic unit, radionuclide data might not exhibit secular equilibrium or cation/anion balances might not be consistent. Simple data analyses, such as those described above, can go a long way to providing an understanding of the data, what the data are trying to convey, compatibility with the CSM, and appropriateness for use of the data in a risk assessment.

7. Data Usability Evaluation Report

The DU Evaluation report should present all data, preferable by exposure area or other decision unit, in tables and on figures. Additionally, all DVSRs and associated laboratory reports should be provided electronically. Simple data analysis results should be presented (summary statistics and plots). Documentation of the DU evaluation should be presented

using one or more of the worksheet templates provided in Attachment A (or similar worksheet, see for example USEPA, 1992a or USEPA, 2002). As discussed above, each data point that was outside of laboratory control ranges should be individually discussed and rationale should be provided as to why the data point was considered usable or not. This evaluation should utilize the DVSR as appropriate. Sample ID(s), lab report(s) and relevant laboratory report pages should be referenced directly to facilitate the review process. If the minimum requirements were not met for the DU Criteria and the data analysis, the specific issues should be discussed and rationale should be provided for why the data were considered usable or not.

8. References

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USEPA, 2002. Risk Assessment Guidance for Superfund (RAGS): Volume 1 – Human Health Evaluation Manual (Part D, Standardized Planning, Reporting and Review of Superfund Risk Assessments), Final. Office of Emergency and Remedial Response, December. http://www.epa.gov/oswer/riskassessment/ragsd/index.htm

USEPA, 2006. Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA QA/G-4. Office of Environmental Information. February. EPA/240/B-06/001. http://www.epa.gov/QUALITY/qs-docs/g4-final.pdf

ATTACHMENT A

Table A-1: Data Usability Evaluation Summary

Data Useability Criterion		Decision	Comments
I	Reports to Risk Assessor		
II	Documentation: (A) Work Plan/SAP/QAPjP		
II	Documentation: (B) SOPs		
II	Documentation: (C) Field and Analytical Records		
II	Documentation: (D) Chain-of-Custody Records		
III	Data Sources: (A) Analytical		
III	Data Sources: (B) Non-Analytical		
IV	Analytical Methods		
V	Data Review		

Table A-1: Data Usability Evaluation Summary

Data Useability Criterion		Decision		Comments
VI	Data Quality Indicators: (A) Completeness			
		Sampling		
		Analytical		
		Combined		
VI	Data Quality Indicators: (B) Comparability			
		Sampling		
		Analytical		
		Combined		
VI	Data Quality Indicators: (C) Representativeness			
		Sampling		
		Analytical		
		Combined		
VI	Data Quality Indicators: (D) Precision			
		Sampling		
		Analytical		
		Combined		
VI	Data Quality Indicators: (F) Accuracy			
		Sampling		
		Analytical		
		Combined		

Example 2 USEPA RAGS Part D

DATA USABILITY WORKSHEET
Site:
Medium:

Activity	Comment
Field Sampling	
Discuss sampling problems and field conditions that affect data usability.	
Are samples representative of receptor exposure for this medium (e.g. sample depth, grab vs composite, filtered vs unfiltered, low flow, etc.)?	
Assess the effect of field QC results on data usability.	
Summarize the effect of field sampling issues on the risk assessment, if applicable.	
Analytical Techniques	
Were the analytical methods appropriate for quantitative risk assessment?	
Were detection limits adequate?	
Summarize the effect of analytical technique issues on the risk assessment, if applicable.	
Data Quality Objectives	
Precision - How were duplicates handled?	

Example 2 USEPA RAGS Part D

Activity	Comment
Data Quality Objectives (continued)	
Accuracy - How were split samples handled?	
Representativeness - Indicate any problems associated with data representativeness (e.g., trip blank or rinsate blank contamination, chain of custody problems, etc.).	
Completeness - Indicate any problems associated with data completeness (e.g., incorrect sample analysis, incomplete sample records, problems with field procedures, etc.).	
Comparability - Indicate any problems associated with data comparability.	
Were the DQOs specified in the QAPP satisfied?	
Summarize the effect of DQO issues on the risk assessment, if applicable.	
Data Validation and Interpretation	
What are the data validation requirements?	
What method or guidance was used to validate the data?	
Data Validation and Interpretation (continued)	
Was the data validation method consistent with guidance? Discuss any discrepancies.	

Example 2 USEPA RAGS Part D

Activity	Comment
Were all data qualifiers defined? Discuss those which were not.	
Which qualifiers represent useable data?	
Which qualifiers represent unusable data?	
How are tentatively identified compounds handled?	
Summarize the effect of data validation and interpretation issues on the risk assessment, if applicable.	
Additional notes:	

Note: The purpose of this Worksheet is to succinctly summarize the data usability analysis and conclusions. Reference specific pages in the Remedial Investigation and/or the Risk Assessment text to further expand on the information presented here.